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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,640	02/07/2001	Babak Nemati		4426

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,640

Applicant(s)

NEMAT, BABAK

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the laser irradiation portion as recited in claim 74, driver portion that drives via iontophoresis, electroporation, acoustic pressure, or application of enhancer, agent, or solvent, as recited in claim 79 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Applicant may conventional features in a labeled rectangular box. The box should be labeled with the specific conventional features Applicant wishes the box to represent.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite in reciting that the apparatus is in a non-invasive position proximal to the sclera, claim 71 (or to the tissue disposed below the permeability layer, claim 78, or the stratum corneum, claim 86). This claim is indefinite because it is not known whether Applicant is reciting the apparatus is non-invasive and proximal to the sclera (i.e., non-invasive to the sclera (or the tissue below the permeability layer), but invasive to the permeability layer) or that the claim requires the apparatus to be proximal to the underlying tissue as well as non-invasive to the permeability layer (i.e., the apparatus would be proximal not only to the underlying tissue but to the permeability layer also).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 71-77, 78, 79, 81, and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by COLEMAN et al.. Coleman discloses an apparatus having a pore forming portion consisting of a needle point, a delivery portion that enables ejection of material from the apparatus into a

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patient (2:63-67), and a non-invasive optical portion coaxial with the pore forming portion. The optical portion is non-invasive because it is recessed from the end of the needle, enabling the optical portion to remain proximal of tissue when the needle end forms a pore. The apparatus is configured to be capable of delivering a clarifying agent to permeability barriers such as sclera or stratum corneum and applying a chemical enhancer or carrier agent.

Claims 71, 72, 75, 76, 78, 79, 81, 83, 84, 86, 87, 88, 89, and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINEZ (U. S. Patent No. 4,222,375). Martinez discloses an apparatus capable of enhancing the optical transparency of biological tissue comprising a pore forming portion (needle 58), delivery portion (syringe 3:25-26), noninvasive optical portion (optical portion 12, coupled to the pore forming portion and delivery portion, remains outside the patient during use). The apparatus is configured such that the opening is formed, agent delivered, and light emitted when the apparatus is proximal to the sclera because the apparatus is capable of applying a chemical force to form pores for the delivery of the clarifying agent. The pore forming portion is the needle 58 that allows agents to be applied to a barrier from a proximal position. In applying penetrating solvents or carrier agents, clarifying agent, and light the apparatus is capable of being proximal to the permeability barrier. See figs. 3, 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 71-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN et al. (US Patent No. 6,275,726) in view of COLEMAN. Chan discloses a pore forming portion as a laser, hypodermic needle, or jet injector (3:64-4:3), delivery portion as a syringe, optical portion for diagnostic and therapeutic applications and to provide spectral information. When using the jet injector embodiment disclosed by Chan the device is non-invasive and is capable of remaining proximal to the barrier (1:50-65; 2:24-32; 3:51-67; 4:1-12; 7:25-65; 8:37-40). Chan does not disclose combining the pore forming portion and light delivery device as coaxially arranged. Coleman teaches incorporating a pore forming portion and light delivery device in one apparatus in a coaxial arrangement to provide for an apparatus that is easy to use and provides fast results (1:29-46). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Coleman in the apparatus of Chan in order to accomplish the precise application of light during surgical operations in an apparatus that easy to use for quick site-specific applications.

Response to Arguments

Applicant argues that the drawings need not show conventional features, but only a "labeled rectangular box." The examiner agrees and requests that Applicant show the conventional features labeled in a box. The label should state the particular conventional feature, not just a general term (i.e., "laser" instead of "Tissue bypass apparatus").

Applicant generally argues that the recited functions and methods of use of the claimed apparatus is not shown in the prior art because the prior art is not capable of performing the

recited use. The examiner disagrees. Applicant has not pointed out any structural differences between the claimed apparatus and the disclosed apparatus in the prior art. Rather, Applicant relies on recited methods of use and argues the prior art can not possibly perform these methods of use. The examiner's position is that the disclosed prior art is capable of performing the claimed functions and discloses all the structural limitations claimed. This functional capability need not be discussed in the prior art, but the prior art must show sufficient structure to be capable of performing the recited use.

Applicant argues that the apparatus disclosed by Coleman must be inserted into the target tissue to work. The examiner disagrees because Coleman is capable of performing the claimed uses. One must look at the structure disclosed by Coleman and determine whether this structure could perform the recited uses. Applicant appears to address the methods that Coleman uses, but would be better served by addressing the structure of the Coleman apparatus. With respect to disclosed structure, Coleman discloses a pore forming portion, delivery portion, and optical portion as recited in the claims. Additionally, the skilled artisan can see that the Coleman apparatus is capable of performing the uses Applicant recites along with the recited structure. Applicant discloses that application of penetrating solvents or abrading the permeability layer is a use for the pore forming portion. The device disclosed by Coleman is capable of performing this use while remaining in a non-invasive position proximal to the sclera.

The prior art disclosed by Martinez is similarly capable of performing the recited function and discloses all claimed structure. Additionally, claim 78 only requires the apparatus to be capable of being in a non-invasive position proximal to the underlying tissue when the clarifying agent is delivered and the light is emitted. During these functions, the apparatus

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disclosed by Martinez is also capable of being located proximal and non-invasive to the underlying tissue and deliver agent and light to the surface of the underlying tissue.

Applicant generally argues that a cannula has a particular meaning in the art that is coupled to a particular use, such as insertion. Applicant appears to argue that a cannula can only be used for insertion. The examiner does not agree. A cannula could be used to bring fluid to the surface of a target site. Applicant's reliance on a particular use of a well-know device is not convincing to withdraw the present rejections.

Applicant argues that the claims require the *entire apparatus*, not just the *optical portion*, to be non-invasive and proximal position. Applicant is arguing a limitation that is not recited in the claims. There is no recitation limiting the position of the *entire apparatus*.

Applicant generally states that he views the rejection of claims 70-90 over Chan in view of Coleman as only addressing claims 72 and 87 that require coaxial arrangement. The examiner maintains the rejection of claims 70-90 over Chan in view of Coleman for "a pore forming portion and light delivery device *in one apparatus*" (claims 70, 71, 73-86, 88-90) "*in a coaxial arrangement*" (claims 72 and 87).

Applicant argues that Chan does not disclose a pore forming portion. The examiner disagrees and maintains that a laser, hypodermic needle, or jet injector is capable of forming a pore and is therefore a pore forming portion of the apparatus.

Applicant generally argues that Chan and Coleman does not disclose the claimed invention having three components and configured "as presently claimed," but does not specifically point out which component is missing from the prior art or what claimed

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configuration is not found in the prior art. The examiner's position, as described above, is maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EDWARDS (US Patent No. 5,833,647) discusses apparatus for delivering agents across permeability barriers. EPPSTEIN (U. S. Patent No. 6,527,716) shows various devices for bypassing a surface permeability layer to deliver agents to covered biological tissues.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
26 June 2005


MICHAEL J. HAYES
PRIMARY EXAMINER